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Driving Innovation:

How Stronger Laws Pull Safer Chemicals into the Market

*By Baskut Tuncak**

Introduction

No one can deny that many of the features of modern life owe much to the ingenuity of the chemical industry. New chemicals, new applications for existing chemicals, and new chemical processes enabled a host of innovations across a range of industries and led to the growth of the chemical industry over the past several decades. Since the 1970s, the output of the chemical industry has grown from approximately US$ 1 trillion adjusted for inflation to US$ 4.12 trillion in 2010, with estimates for 2020 approaching US$ 6.5 trillion.[1] As the scale of the chemical industry has grown so too has evidence of the adverse effects of chemicals on human health and the environment.

Innovation is especially relevant today as the establishment of the chemical industry, from manufacturers to formulators, face increasing pressure from two fronts.[2] First, after overtaking traditional leaders such as the United States and Western Europe in bulk chemical manufacturing, emerging economies are positioning themselves to become leaders in chemical innovation.[3] Simultaneously, the chemical industry is also facing increasing pressure from downstream users, retailers, and consumers to provide safer products through the development and use of safer chemicals.

A common refrain by the regulated (or soon-to-be regulated) industry is that stricter laws over hazardous chemicals will impede innovation, reducing economic growth, competitiveness, and employment. We define "laws" to include legislation, regulation, directives, decisions, rules, and other forms of enforceable standards at the sub-national, national, regional, and global level. Current laws in the European Union and United States designed to protect people and the environment from hazardous chemicals aim to enhance innovation.[4] However, both European and American laws have shortcomings in terms of their ability to prevent harm, the costs of which are borne by individuals and society-at-large, and to encourage the entry of safer alternatives. Can stricter laws over hazardous chemicals drive innovation? Can it drive innovation while also sending it in a safer direction?

Reviewing recent measures to reduce the risk of harm from additives to plastics (phthalates), toxic flame retardant chemicals ("PBDEs"), refrigerants ("CFCs"), and pesticides (methyl bromide), this article focuses on the features of policies that stimulated innovation and the factors that led to satisfactory or unsatisfactory outcomes. Examining patents as an indication of rates of invention, this article explores the types of inventions that downstream users and consumers in the market subsequently adopted.

This article presents findings regarding the efficacy of past measures and the potential of stricter laws to accelerate innovation toward safer chemicals. First, the article presents findings on the human health effects of hazardous chemicals, illustrating the pressing need for innovation around safer chemicals. The next section discusses the rate at which alternatives are invented in response to the prospect of stricter laws. Then, the article examines the types of inventions adopted by downstream users after regulators take measures, exploring why the transition may or may not have been to safer alternatives. Fourth, the article looks at how the law can help safer alternatives overcome barriers to entry, enabling early adopters to gain competitive advantage through innovation and an opportunity to optimize their return on new investments. The final section presents findings on how stricter laws direct resources to the innovation of safer alternatives.

Human Health Effects Linked to Hazardous Chemicals

As the scale of the chemical industry has grown since the 1970s so too has evidence of the adverse effects of chemicals on human health and the environment. According to Eurostat, the share of toxic chemicals in the total production of chemicals is at 62%.[5] Analyses of household cleaners, plastic products (including toys), clothing, and other everyday products show that many such products can contain over seventy chemicals considered of very high concern.[6] Recent biomonitoring studies confirm the migration of hundreds of hazardous chemicals from everyday products into people, either directly, or through food, water, air, household dust, and other sources.[7] Of significant concern is the exposure of children to a potent cocktail of hazardous chemicals during critical windows of development. These exposures occur through their mother's womb and breast milk, as well as from broader environmental sources mentioned above. The effects of exposure to these chemicals at an early age often do not manifest for many years or even decades.

There is an increasing incidence of many diseases around the world, including many that were much less prevalent in children in decades past. These trends include:

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- A 24% increase of childhood cancers such as leukemia and brain cancer since 1975 and a forty percent increase in the incidence of breast cancer between 1973 and 1998;[8]
- Asthma, which approximately doubled in prevalence between 1980 and 1995, continues to rise;[9]
- Forty percent more women reported difficulty conceiving and maintaining a pregnancy from 1982 to 2002. From 1982 to 1995, the incidence of reported difficulty almost doubled in younger women, ages 18–25;[10]
- Sharp increases in male genital malformations;[11]
- Learning and developmental disabilities, including autism and attention deficit hyperactivity disorder, affect nearly one in six U.S. children, as of 2008;[12]
- Doubling of the rate of diabetes in the United States and England, with increasing frequency among young populations;[13] and
- Dramatic rise in the prevalence of obesity among both older and younger populations, and both wealthy, industrialized countries as well as poorer developing countries.[14]

There is growing consensus about the role of chemicals in the increasing incidence of many disorders around the world. Among many factors, there is increasing evidence that exposure to endocrine disrupting chemicals ("EDCs") at an early age is linked to many of these disorders.[15]

An EDC is a chemical, or mixture of chemicals, that interferes with any aspect of hormone action.[16] Suspected EDCs are commonly found in people, wildlife, and the environment. Over 800 chemicals have been identified as having endocrine disrupting properties.[17] All of the twenty-two chemicals listed under the Stockholm Convention, a global treaty that restricts or bans some of the most hazardous chemicals used around the world, have endocrine disrupting properties.[18]

The adverse effects that are increasingly linked to exposure to chemicals with endocrine disrupting properties include: effects on reproduction, such as infertility and reduced sperm count and viability; breast, mammary, testicular, and prostate cancers; type 2 diabetes, obesity, and heart disease; neurobehavioral outcomes; and thyroid and immune system dysfunction.[19]

There are several key features of endocrine disrupting chemicals that make exposure to any dose of an EDC unsafe, including effects at low doses,[20] cumulative effects,[21] permanent adverse effects during critical developmental windows,[22] effects on future generations,[23] and ubiquity in the environment.[24]

Stricter Chemical Laws Spark the Invention of Alternatives

A common argument against the prospect of stricter rules to protect people and the environment from hazardous chemicals is that there is not a viable alternative to the chemical.[25] This argument might be made for technical reasons, such as the "performance" of the chemical relative to alternatives, or the lack of manufacturing capacity for alternatives. It can also be made for economic reasons, where an alternative is argued to be prohibitively expensive. Restricting or banning the chemical of concern would, the argument goes, reduce the competitiveness of a product or may even result in the unavailability of a product or process from the market altogether. The argument is essentially a threat of lost profits, jobs, and competitiveness at the global level.[26]

These arguments, however, ignore our ability to invent better solutions and re-design the way people interact with their environment. This section reviews chemicals of concern, ranging from industrial chemicals in consumer products to pesticides, under national, regional, and global environmental laws. Review was limited to chemicals that have sufficient information about their hazardous properties and are subject to significant scrutiny in more than one region of the world. In each case, the prospect of stricter rules for certain chemicals sparked the invention and development of alternatives, including incremental improvements in the performance of pre-existing alternatives.[27] Stricter laws are defined as those that: (a) require a significant reduction in exposure to hazardous chemicals; (b) require compliance through the use of comparatively costly technology; or (c) require significant technological change.[28] Below are findings for two chemicals or classes of chemicals of concern that also clearly illustrate this trend: phthalates, a widely used endocrine disrupting chemical; and chlorofluorocarbons, an ozone depleting substance.

Phthalates

Phthalates are a class of chemicals used as plasticizers to soften certain plastics. Ninety percent of phthalate production, estimated to be in the millions of tons per year, is used to plasticize polyvinyl chloride ("PVC").[29] As a plasticizer, phthalates are not bound to the plastic polymer, so they leach out of products, resulting in exposure for people and wildlife and contaminating homes and the environment.[30] Phthalates are also used as solvents in many cosmetics that are applied directly to the skin, including perfumes, lotions, soaps, shampoos, deodorants, and hair care products.

Certain phthalates are widely recognized as EDCs. Some disturbing genital deformations associated with phthalate exposure in animals have earned the title of "phthalate syndrome."[31] Other potential adverse effects include cancer, obesity, diabetes, and attention deficit hyperactivity disorder.[32] Like other EDCs, these effects are believed to correlate with exposure during critical windows of development. Recent studies have detected phthalate metabolites in a high percentage of people tested. Some cases found phthalate metabolites in all urine samples analyzed.[33]

Beginning in 1998, following European leadership, countries around the world took measures to protect human health from certain hazardous phthalates. In addition to the Member States of the European Union ("EU"), Canada, Japan, Iceland, Mexico, Norway, Argentina, Tunisia, and the United States are among the many countries that took measures to ban or restrict the use of certain phthalates. The EU added four of these phthalates (BBP, DEHP, DBP, and DIBP) to the EU's REACH Candidate List, and subsequently the REACH Authorization List.[34] Through their inclusion on the Authorization List, all uses of these phthalates in the EU are required to cease by February 21, 2015, unless for a specifically authorized use.[35] Certain Member States of the EU continue to pursue more stringent domestic measures than measures at the regional level.[36]

These measures may have sparked the invention of alternatives to certain uses of phthalates. Publicly available patent records illustrate a surge of inventions (measured by "patent families") to eliminate exposure to phthalates. There is a noticeable acceleration in the filing of patents, and thus the pace of invention, beginning around 1999, following the initial EU measures, and accelerating again in 2006, around the adoption of REACH. These time points correlate with years in which Europe led the world in adopting measures to reduce the use of certain phthalates.

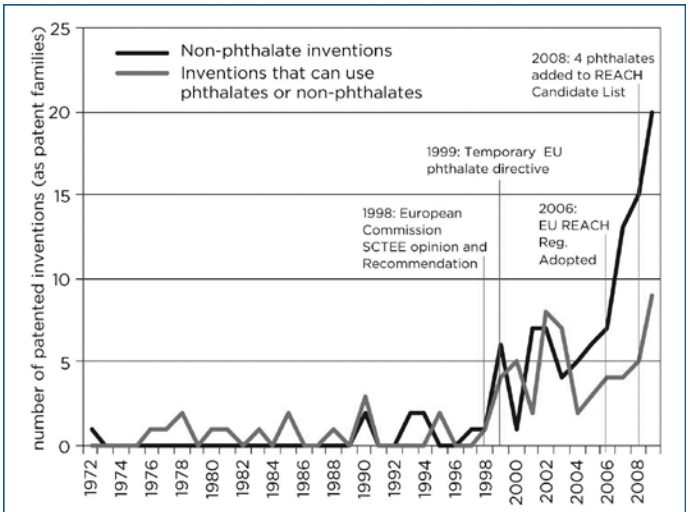

Figure 1. Spike in Patented Inventions Free of Hazardous Phthalates.

Considering the varying degree of research and development required before filing a patent, inventors likely foresaw the enactment of stricter laws and began research necessary for the patent application beforehand, filing when new laws appeared imminent to maximize their time-period of exclusivity under the patent.[37] Because these events took place long before compliance deadlines, companies were afforded the necessary lead-time to develop and possibly patent their technological inventions. For example, the EU's temporary directive in 1999 was proceeded by a Recommendation by the European Commission in July 1998, which itself was preceded by an opinion of the European Commission's Scientific Committee on Toxicity, Ecotoxicity, and the Environment in April 1998.[38]

The correlation of increased invention in response to the prospect of stricter laws is consistent with other lessons of the past. For example, investigations of regulatory events surrounding lead, mercury, polychlorinated biphenyls ("PCBs"), and vinyl chloride also confirm that informal regulatory procedures before rulemaking began drove companies to develop their technological responses.[39]

Yet it was not until significantly strict measures appeared likely (inclusion in the Authorization List under the EU's "REACH" Regulation) that major chemical manufacturers and others significantly increased their patenting of alternatives. Nearly one-half of the patented inventions claiming an alternative to phthalates reference the health and environmental concerns surrounding this class of chemicals.

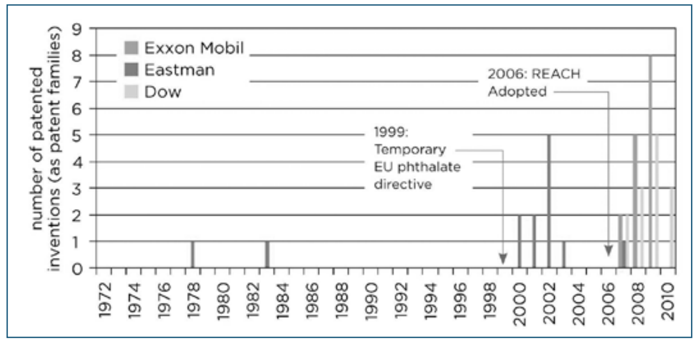

Figure 2. Stricter Laws Trigger Innovation by Major Chemical Manufacturers.

Following Evaluation of the information provided, an EU Member State or the European Chemical Agency ("ECHA") may propose to identify a chemical as a Substance of Very High Concern ("SVHCs")[40] and place it on the REACH "Candidate List." Subsequently, ECHA can recommend a chemical on the Candidate List for Authorization. If approved by the European Commission, the chemical is placed on the REACH Authorization List, in which case companies must request authorization for specified uses after a "Sunset Date."

According to the European Commission's interim evaluation of the impact of REACH on innovation in Europe ("REACH Innovation Report"), "the Candidate List is a, if not *the*, major driver for change at present."[41] As more information about the intrinsic hazards of chemicals within the scope of REACH becomes available, the Candidate List stands to continue to drive innovation in the chemical industry.[42] With broad criteria for identifying endocrine disrupting chemicals and information about endocrine disrupting properties of chemicals, it stands to reason that the Candidate List will further drive innovation.

CFCs

Chlorofluorocarbons ("CFCs") displaced ammonia, sulfur dioxide, carbon dioxide, and other "natural" refrigerants in the 1930s. Unlike these refrigerants, countries adopted CFCs because they offered a safer alternative in terms of their toxicity, flammability, and/or energy efficiency.[43] Unfortunately, it was not until many decades later that these chemicals were widely acknowledged to be ozone depleting substances.[44] Other uses for CFCs included foam production (e.g. Styrofoam™), aerosol products, and solvents for cleaning products with delicate components such as electronics.

Chemical companies were alert to the human health and environmental consequences of CFC emissions as early as 1972. Following a 1972 conference, DuPont and other CFC manufacturers formed a consortium coordinated by what is now the American Chemistry Council ("ACC"), a U.S. trade association for chemical manufacturers.[45] When ozone depletion resulting from CFC emissions began to gain substantial mainstream attention in 1974, members of the consortium defended the continued

Table 1. Intrinsic properties of various chemical refrigerants.

Chemical	Ozone depleting potential (relative to CFC-11)	Global warming potential (relative to CO_2)	Other hazardous properties
Ammonia*	0	< 1	Highly toxic (but odor enables evacuation), slightly flammable
Carbon Dioxide*	0	1	Toxic at high doses
CFC-11	1	4,600	
CFC-12	0.820	10,600	
HCFC-22	0.034	1700	
HFC-134a	0	1300	
Hydrocarbons*	0	~20	Flammable

*"Natural" refrigerants[53]

use of CFCs, and called for additional scientific evidence, insisting their chemicals were safe until proven otherwise. They also argued that health and wealth would decline in a world without CFC products.[46]

Simultaneously, research and development into alternatives was well underway, with several alternatives identified. During debate over stricter measures on CFCs and other ozone depleting substances, representatives of DuPont and other CFC manufacturers stated that they had identified technically viable alternatives to CFCs between 1975 and 1980 but could not introduce these alternatives because, by their estimates, the alternatives would not be economically viable.[47] Later, these manufacturers acknowledged that it was the lack of legally-enforceable standards that prevented the entry of safer alternatives.[48]

The United States, Canada, Sweden, and Norway announced plans to ban non-essential aerosol products in 1976, aided in part by slumping sales of CFC-containing products due to consumer concern. These laws at the national level spurred changes in the industry, most notably in the United States. Changes in the U.S. industry in turn positioned the United States well to push more actively for international laws over ozone depleting substances, given its own competitive advantage.[49]

In 1987, countries around the world agreed on a timeline for the global phase out of CFCs under the Montreal Protocol.[50] A patent search by the World Intellectual Property Organization showed that various chemical manufacturers and other diversified businesses in both Japan and the United States patented a variety of processes, including the process for the manufacture of one of the most widely used alternatives to CFCs, hydrofluorocarbon (HFC)-134a, in 1987 and 1988.[51]

Thus, the prospect of stricter laws at the national and global level spurred inventors to research alternatives to CFCs and hydrochlorofluorocarbons ("HCFCs"), leading to the development of both HFCs and inventions for the safer use of "natural" refrigerants (used in the 1930s before CFCs) as alternatives to CFC refrigerants.[54] HFCs prevailed over ammonia, carbon dioxide ("CO_2"), and other "natural" refrigerants due to the cost advantages. However, while HFCs are not ozone depleting substances, they are potent greenhouse gasses. Aided by stricter rules in Europe that phased out HFCs in new cars after 2011

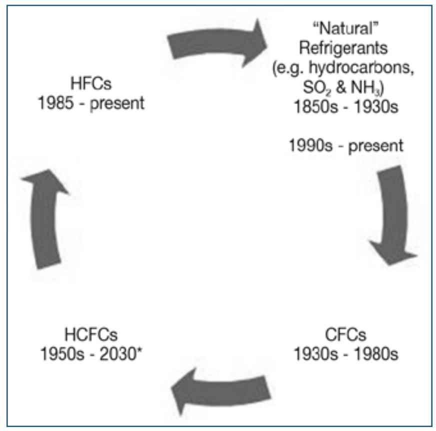

Figure 3. Innovation Cycle of Refrigerants. Innovation of various chemical refrigerants over the 20th and 21st centuries. Dates are approximations based on major usage and expected reductions under national and international agreements.[52]

and public campaigns to use hydrocarbons in domestic refrigerators, considerable research and development continued around the use of natural refrigerants.[55] Incremental inventions enabled these "natural" refrigerants to overcome properties deemed undesirable almost a century ago (see Table 1). With the continued development of natural refrigerants, hydrocarbon domestic refrigerators are now economically viable and commonly available in Europe and Asia, with both environmentalists and manufacturers alike advocating for the United States to adopt them as well.[56] In addition, suppliers of equipment using ammonia rather than HCFCs recaptured market share in cold storage and food freezing.[57]

The prospect of progressively stricter laws over CFCs and other ozone depleting substances sparked the continuous invention of alternatives, including improved methods of using natural refrigerants, making the chemicals once displaced by CFCs a viable alternative to ozone depleting substances and greenhouse gasses.[58] Together, the experiences of both phthalates and CFCs illustrate how the systematic introduction of progressively stricter rules at the global and regional levels spurred the continuous invention of safer chemicals, averting the serious consequences of inaction and disproving the estimated cost of action.

Chemical Laws Can—But Not Always Do—Pull Safer Inventions Into the Market

For quite some time I have been confronted with problems from the plasticizers in vinyl for aerospace applications and I *have long since come to the conclusion that vinyl should not be permitted in any phase of aerospace usage . . . . [S]ubstitute polymers for the vinyl are readily available and in many cases they have far superior physical properties at a small sacrifice in immediate cost.*

—Frederick G. Gross, NASA Materials Engineering Branch, April 26, 1971[59]

Innovation hinges on the adoption of an invention. As illustrated above, chemical laws can accelerate the invention of alternatives to hazardous chemicals. To replace widely used hazardous chemicals, inventors created new chemicals and processes, developed new uses for existing chemicals, and found alternative approaches. The spike in invention to eliminate certain phthalates shows that environmental laws can be a critical element—a driver—in accelerating invention in the chemical industry.

Chemical laws can also pull inventions into the market, thereby turning invention into innovation. The above examples of CFCs and phthalates illustrate this. Some of the alternatives used for certain phthalates and CFCs existed well-before the prospect of stricter laws was on the horizon. Until the prospect of enacting stricter restrictions on the use of these entrenched and hazardous chemicals, companies sidelined these alternatives, with far less opportunity for adoption in the market and further development through experience gained from their successes and shortcomings.

Some of the replacements for chemicals of concern, however, have been very unsatisfying. History is replete with examples of regrettable substitution, where years of concerted effort is undertaken to restrict or phase-out an individual chemical of concern, only to see the chemical replaced with a different chemical of concern.[60] This unsatisfying transition has undermined the confidence of the public and businesses in the ability of innovation alone to ensure meaningful progress towards safer alternatives. Below, is a cross-section of examples of substitution, ranging from clearly regrettable substitutes, to the entry of alternatives that raise questions, and finally, to more promising examples.

Regrettable Substitution

Over the last several decades, demand for chemical flame-retardants has accelerated. Production increased from just over 500 million pounds in 1983, to 3.4 billion pounds in 2009, and projections expect it to jump another 30% to 4.4 billion pounds by 2014.[61] The transition away from toxic flame-retardants provides one example for regrettable substitution.

Polychlorinated biphenyls ("PCBs") and polybrominated biphenyls ("PBBs") were widely used as flame-retardants until the 1970s, when health and environmental concerns began to surface.[62] When PCBs and PBBs were banned as flame-retardants, polybrominated diphenyl ethers ("PBDEs") took their place in the market as flame-retardants. Under U.S. and European laws at the time, PBDEs were considered "existing" chemicals, meaning no evidence of safety was required for these chemicals to remain on the market when industrial chemical laws were passed in the 1970s in the United States and Europe.[63] Production and use increased rapidly for PBDEs over the next several decades as new markets for them emerged, or were created, including furniture foam, electronics, textiles, and baby products.[64]

Overwhelming evidence has emerged about the hazards of PBDEs, including their endocrine disrupting properties.[65] Not only do these chemicals exhibit toxicity at both high and low-doses, but they persist in the environment rather than breaking down into safer constituents, accumulate in living organisms, and travel long distances by wind, water, animals in which they have accumulated, and products traded internationally. As evidence of the dangers of PBDEs grew overwhelming, many countries around the world began to phase out certain PBDEs, creating the possibility for the entry of safer alternatives.[66] In other countries, manufacturers of PBDEs agreed to voluntarily discontinue the production and sale of these chemicals. The Stockholm Convention, a global treaty that applies to some of the world's most hazardous chemicals, banned two types of PBDEs in 2009.[67] PBDEs are one example of regrettable substitution among a cluster of toxic flame-retardants.

Unfortunately, one of the replacements for certain PBDEs is yet another episode of regrettable substitution. The U.S. Environmental Protection Agency ("EPA") approved Firemaster 550™, a mixture of several chemicals, in 2003 under the U.S. Toxic Substances Control Act's ("TSCA") provisions for the approval of new chemicals.[68] Because of the limited power for regulators to demand sufficient proof of safety before companies produce a new chemical for use, the EPA could only use the scant information provided by the manufacturer, Chemtura, and computer models to predict the chemical mixture's toxicity. According to a U.S. EPA official, "[w]e didn't think [Firemaster 550™] would bioaccumulate, but it turns out that prediction isn't borne out by reality."[69]

Regulators in the United States approved Firemaster 550™ for use, even though it had suspicions, including the structural similarity of a chemical ingredient of Firemaster 550™ to DEHP, a phthalate restricted from certain uses due to evidence that it is a reproductive toxin. U.S. authorities asked Chemtura to provide additional studies. Chemtura provided two of its own studies, five years later, which showed adverse effects at high-doses, such as skeletal malformations and low-birth weight. But the company argued that these results were inconclusive.[70]

Although advertised as a "green" replacement to PBDEs,[71] evidence continues to emerge that one or more ingredients of Firemaster 550™ are released from products containing the mixture, could be toxic, accumulate in wildlife, travel long-distances through the environment, and may have adverse effects at low doses.[72] Like PBDEs and structurally similar phthalates, recent studies indicate that some of Firemaster 550™'s ingredients have endocrine disrupting properties.[73] Yet Firemaster 550™ remains in use.

More Promising Examples of Substitution

Chemists have discovered ways to design chemicals to make them inherently safer. An older example is the ability to design chemicals so that they do not persist as long in the environment.[74] One such technique is the use of secondary nitrogen atoms instead of tertiary nitrogen atoms to enhance biodegradability, as demonstrated with the use of ethylenediamine-N,N'-disuccinic acid ("EDDS") instead of ethylenediaminetetraacetic acid (EDTA) as a complexing agent. Complexing agents like EDTA can be used to improve cleaning efficiency by sequestering metals in water-based solutions, but they also raise concerns about their ability to mobilize toxic metals in the environment.[75] Some countries and regions have phased out EDTA for certain applications.[76] EDDS is far more biodegradable than EDTA and also performs better as a complexing agent in some applications.

With the increasing stringency of measures on the use of certain phthalates, including the scheduled phase out of four phthalates (DEHP, DBP, BBP, and DIBP) from certain products in the European Union by February 21, 2015, alternatives are increasingly being demonstrated as viable and adopted.[77] While some phthalate-based alternatives raise questions, other alternatives to phthalates show more promise.

For example, experiments with different types of raw materials as feedstocks have resulted in a castor-oil-based alternative to phthalate plasticizers for PVC (Soft-n-Safe™). It has been approved for use in food contact surfaces, vinyl flooring and wallpaper, toys, medical devices, inks, textile dyes, and other applications.[78] This direct substitute does not exhibit many of the intrinsic hazards of phthalates and other plasticizers. Notably, and unlike the phthalates they replace, studies show no evidence of endocrine disruption or other adverse effects for this alternative.[79]

In the effort to remove phthalates from products, other companies have removed a principle reason phthalates are used in the first place—PVC. For example, office products retailer Staples® removed PVC from its packaging materials.[80] Downstream users are also removing phthalates by removing the PVC. Of particular concern is the use of phthalate-containing PVC for blood bags and other infusion/transfusion sets, which can subject very young children to hazardous levels of the phthalate DEHP during critical windows of development. As a result of recent measures for particular phthalates, medical suppliers that provide phthalate-free alternatives to PVC medical devices are experiencing a boom in both demand and growth.[81]

Innovators have also found safer alternatives to treating furniture foam with toxic chemicals to prevent furniture fires. For example, specially designed upholstery can resist smoldering cigarettes, preventing underlying foam from igniting. In addition, researchers developed non-toxic fire-resistant barriers, adopted by mattress manufacturers. Both of these alternatives are far more effective at slowing fire than adding flame retardants to foam, which in fact does not slow the fire by any significant degree according to several tests by government agencies and independent laboratories.[82]

The above examples illustrate how invention has been sparked by laws to reduce or eliminate hazardous chemicals. First-movers may have a considerable advantage over competitors as demand and requirements for safer products increase.

Requirements for Stricter Chemicals Laws

Legal controls cleared the way for the adoption of alternatives, pulling newly developed or pre-existing solutions to occupy the space vacated by certain hazardous chemicals. In order to increase the likelihood that safer alternatives will be pulled into the market, the law needs to clearly identify hazardous properties that are not acceptable in society and require their substitution with safer alternatives (including non-chemical alternatives) in a systematic way. For example, the EU's REACH authorization procedure gives a clear signal to industry that chemicals that are carcinogens, mutagens, or toxic to reproduction, and those that exhibit persistence and bioaccumulation, need to be substituted with safer alternatives.[83] This provides clear direction to chemical manufacturers and downstream users of chemicals that they must innovate away from chemicals with these properties.

The availability of information about chemical hazards and the prospect of regulatory action accelerate research towards safer solutions, whether it is through the invention of new chemicals, new applications of existing chemicals, new materials, or new processes.[84] But more critically, stricter requirements that chemical manufacturers generate information about intrinsic hazards and exposures can drive innovation in a safer direction. Without information about the full scope of intrinsic hazards of all chemicals, downstream businesses are highly vulnerable to investing in the substitution of one hazardous chemical with a different hazardous chemical. Some might say they risk jumping from the frying pan into the fire.

The surge in the invention of alternatives to phthalates began the same time as European laws limited the use of six widely used phthalates in toys and other children's products, a small percentage of global phthalate use.[85] To some degree, both the number of phthalates and the number of products within the scope of laws around the world are increasing and stand to increase further as the deadline for authorization of uses for certain phthalates approaches in the EU.[86] This trend towards stricter laws over the use of phthalates spurred the invention of phthalate alternatives beyond the miniscule share of the market occupied by toys and children's products.[87]

The ability of chemical laws to pull inventions into the market is a crucial aspect of the potential power of chemicals policies to spur innovation toward safer alternatives. Businesses may argue that environmental laws follow the invention of alternatives to hazardous chemicals and thus are not a driver of innovation. But it is the prospect of stricter measures that often drives the research and development of new ideas and later enables the entry of these ideas into the market.[88] The acceleration in the number of non-phthalate and phthalate-free patents illustrates how the prospect of progressively stricter rules against the use of hazardous chemicals can incentivize, or push, companies to develop alternatives (see Figures 1 and 2).

Part of this ability comes from the power of the law to enable new ideas, safer alternatives in this case, to overcome barriers to entry. Even if a safer alternative to a chemical of concern is invented and available for adoption, there are many factors that present barriers to its entry into the market.

One factor is the substantial economies of scale for existing chemicals.[89] These economies of scale result not only from the economies inherent in higher production volumes but also from long periods in which innovations could occur around their production and use, with resulting increases in efficiencies and demand.[90] The discovery of new uses, increasing production volumes and the development of more efficient processes for chemical synthesis enable existing chemicals to become more and more entrenched in products and processes.

Second, the continued externalization of costs by the chemical industry makes it difficult for safer alternatives to compete on a level playing field.[91] Externalities are costs or benefits arising from an economic activity that affect somebody other than the people engaged in the economic activity and are not reflected fully in prices.[92] Recent analyses by the United Nations Environment Programme ("UNEP") highlight the cost of inaction for the sound management of chemicals on human health and the environment, with large burdens falling on individuals and government budgets. These reports conclude that, "the vast majority of human health costs of chemical production, consumption and disposal are not borne by chemical producers, or shared down the value-chain. Uncompensated harm to human health and the environment are market failures that need to be corrected."[93]

A third factor is an inability of businesses, consumers, and regulators to access information about the hazards of chemicals and products containing hazardous chemicals.[94] The vast majority of chemicals lack adequate information about their adverse effects, such as their potential for endocrine disruption.[95] This is due in large part to chemical policies adopted around the world in the 1970s that presumed the safety of nearly all chemicals in commerce. Policies have changed in Europe and elsewhere to require basic information on the most widely used industrial chemicals. For example, 72% of businesses surveyed responded that REACH had led to increased access to information about chemicals.[96] Small firms benefited more than larger firms in terms of conception of products resulting from increased information enabled by REACH, in particular information about hazardous substances communicated along the supply chain (through Safety Data Sheets).[97]

Despite information generated to date under REACH, the ongoing dearth of information remains a concern. As information is generated in the coming years for "existing" lower production volume chemicals, the benefits of information generated by REACH for innovation is likely to grow.[98]

Stricter chemical laws can help to pull inventions into the market. But, safer chemicals will continue to face an uphill battle in displacing hazardous chemicals as long as: (1) economies of scale are not addressed; (2) the costs of hazardous chemicals remain externalized to the public; and (3) information asymmetries continue to exist. Effective chemical laws can and must address these factors, enabling the adoption of safer chemicals and thus innovation towards safer products and processes.

Stricter Chemicals Laws Direct Resources Toward Innovation and the Development of Safer Alternatives

It is argued that strict regulation entails unnecessary costs to the regulated industry and hampers the introduction of certain inventions. Ideally, inventions not allowed onto the market would be those that are dangerous to human health or the environment or are otherwise undesirable. Achieving the appropriate balance between measures to protect human health and the environment on the one hand, and the freedom to experiment and develop better solutions to problems on the other, is something most stakeholders can agree upon, although where this balance lies is at the center of many contentious debates.

Responding to a survey commissioned by the European Commission about the impacts of EU REACH on innovation, some businesses claimed that there has been a significant redirection of skilled personnel from R&D and innovation-related activities to compliance work as a result of the implementation of the regulation.[99] But since the 1970s, scholars have questioned the notion that stricter laws direct resources away from R&D and innovation-related activities.[100] Scholars conclude from these studies that, "innovation is indeed being changed by regulation, but that there is a redirection of innovative efforts into more socially approved areas, rather than an absolute decline."[101] Overall, responses tended to reflect the European Commission's Economic Impact Analysis: negative effects of having to meet compliance requirements could dominate in the short term, with significant positive impacts on innovation expected in the longer term.[102]

Other findings of the independent survey suggest that, in fact, more resources have been directed towards innovation as a result of the EU's REACH Regulation. For example, regarding the impact of REACH on innovation, nearly half of survey respondents report that as a result there has been an increase in expenditure on research and development ("R&D") and related innovative activities.[103] Two reasons were suggested for this increase: the inability to stop innovation programs that were of strategic importance to the firms in question, and—most significantly—*the creation of new opportunities due to the coming into force of the REACH Regulation*.[104]

Of concern during debates over the possible impact of REACH's requirements was the impact of the Regulation on innovation by small and medium-sized enterprises ("SMEs"). Notably, small, medium and large businesses were all among those reporting an increase in expenditure on R&D in response to the stricter requirements of REACH.[105]

In short, regarding the overall effect of mechanisms within REACH on the willingness and determination of businesses to innovate, the REACH Innovation Report concludes that despite having to bear the additional costs of REACH, firms have continued to innovate and are keen to continue to do so.[106]

Moreover, some of the responses illuminate the potential for the creation of new, highly specialized jobs. As information comes due for submission for an increasing number of chemicals under REACH, it is believed that demand for human resources with technical and regulatory expertise will increase.[107] Universities responded to this new demand by developing chemistry curricula with a specialization in REACH. The authors of the REACH innovation report conclude that as a result of REACH, "it is envisaged that over time the number and quality . . . of skilled human resources to industry will increase and be supportive of innovative activity."[108]

The above patent findings also support the conclusion that stricter rules for chemical safety can drive greater resources towards invention and innovation. The above-mentioned acceleration in the number of patents claiming phthalate-alternative or phthalate-free invention is one indication of an increase in resources towards invention and innovation. Indeed, the most active companies are some of the biggest manufacturers of phthalates—Exxon Mobil, Dow, and Eastman Kodak/Eastman Chemical (see Figure 2). In addition to these three large chemical manufacturers, the study found that eighty-five other companies obtained at least one patent for a "non-phthalate" or "phthalate-free" invention.

The most common phthalate measure restricts six phthalates above a certain concentration in toys and children's products. However, the study found that approximately 95% of the patents identified were not limited to infant and children's products. Moreover, inventions were disclosed for the use of phthalates in a range of products, much broader than the limited market segment singled out under the law.[109] These patent filings suggest that as the likelihood of stricter rules over existing chemicals of concern increased, resources were devoted to innovation to maintain or even capture market share.

Thus, while some may argue that stricter rules for ensuring chemical safety may direct resources away from innovation, recent experiences suggest that the desire to maintain market share by industry is sufficient to direct resources towards the innovation of safer alternatives and the development of new, innovation-friendly skills.

Conclusion

Consumers, downstream users, and investors are increasingly demanding products free of hazardous chemicals throughout their life-cycle. In addition to customer demand, businesses increasingly recognize that the transition away from hazardous chemicals is often accompanied by the emergence of a competitive advantage and market opportunities. Effective chemical policies must be in place to reward businesses that develop safer approaches by enabling their ideas to replace those that are less safe.

The question is then how to spur the innovation of approaches that stand to provide the most improvement to people, wildlife, and the environment from the status quo of chemicals. And then, for those inventions that are indeed a safer alternative, how to effectively overcome barriers to entry so that these safer alternatives can displace incumbent hazardous chemicals and production processes in the marketplace.

The findings of this study suggest that progressively stricter laws, with a gradual phase-out of chemicals with certain intrinsic hazards, spur the innovation of alternatives, with the potential to pull safer alternatives into the market, enabling them to overcome barriers to entry. This enables innovators that seek comparative advantages to continuously innovate towards the safest alternative for various uses and allows predictability for industry and investors.

Endnotes: Driving Innovation: How Stronger Laws Pull Safer Chemicals into the Market

[1] *See* UN Env't Programme , Global Chemicals Outlook (Sept. 5, 2012), *available at* http://www.unep.org/pdf/GCO_Synthesis%20Report_CBDTIE_UNEP_September5_2012.pdf [hereinafter UNEP]; Org. for Econ. Cooperation & Dev. (OECD), Environmental Outlook for the Chemicals Industry (2001), *available at* http://www.oecd.org/dataoecd/7/45/2375538.pdf [hereinafter OECD]; *CPI Inflation Calculator*, Bureau of Labor Statistics, http://www.bls.gov/data/inflation_calculator.htm (providing inflation-adjusted dollar values).

[2] In this report, we adopt the definition of innovation used in the Oslo Manual. *See* OECD & Statistical Office of the European Communities (Eurostat), Oslo Manual: Guidelines for Collecting and Interpreting Innovation Data 46 (3rd ed. 2005), *available at* http://www.uis.unesco.org/Library/Documents/OECDOsloManual05_en.pdf [hereinafter Oslo Manual] (defining innovation as "the implementation of a new or significantly improved product (good or service), or process, a new marketing method, or a new organizational method in business practices, workplace organization or external relations.").

[3] *See* OECD, Environmental Outlook to 2050: The Consequences of Inaction (2012), *available at* www.oecd.org/environment/outlookto2050; UNEP, *supra* note 1, at 13-14.

[4] *See* Commission Regulation 1907/2006, art. 1(1), 2006 O.J. (L 396); U.S. Toxic Substances Control Act, 15 U.S.C.A. § 2601(b)(3) (2014). *See also* EU Plant Protection Products Regulation (PPPR), Directive 98/8/EC of the European Parliament and of the Council of 16 February 1998 Concerning the Placing of Biocidal Products on the Market, 1998 O.J. (L 123).

[5] *See* Eur. Comm'n & Eur. Env't Agency, Environment and Human Health 21 (No. 5/2013).

[6] *See* UNEP, *supra* note 1, at 28 (citing MSCI and ChemSec, 2011).

[7] *See* Ctr. for Disease Control (CDC), Fourth National Report on Human Exposure to Environmental Chemicals 321 (2009), *available at* http://www.cdc.gov/exposurereport/pdf/FourthReport.pdf. *See also* Consortium to Perform Human Biomonitoring on a European Scale (COPHES), Human Biomonitoring for Europe, http://www.eu-hbm.info/cophes.

[8] Safer Chemicals, Healthy Families, Chemicals and Our Health: Why Recent Science is a Call to Action 3 (July 2012), *available at* http://saferchemicals.org/PDF/chemicals-and-our-health-july-2012.pdf.

[9] *Id*.

[10] *Id*.

[11] *Id*.

[12] *Id*.

[13] Miquel Porta & Duk-Hee Lee, ChemTrust, Review of the Science Linking Chemical Exposures to the Human Risk of Obesity and Diabetes 4-5 (Jan. 2012), *available at* http://www.bund.net/fileadmin/bundnet/pdfs/chemie/20120320_chemie_diabetes_report.pdf

[14] *Id*.

[15] *See* World Health Org. (WHO), Endocrine Disruptors and Child Health: Possible Developmental Early Effects of Endocrine Disruptors

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on Child Health 1-2, 49-50 (2012), *available at* http://apps.who.int/iris/bitstream/10665/75342/1/9789241503761_eng.pdf.

16 *TEDX List of Potential Endocrine Disruptors*, The Endocrine Disruption Exchange, http://endocrinedisruption.org/endocrine-disruption/tedx-list-of-potential-endocrine-disruptors/overview [hereinafter TEDX] (last visited Mar. 27, 2014).

17 *Id*.

18 *Id.*; Stockholm Convention on Persistent Organic Pollutants (POPs), May 22, 2001, 2256 U.N.T.S. 119, Annex.

19 Safer Chemicals, Healthy Families, *supra* note 7, at 15-16; Porta, *supra* note 8, at 12-14.

20 Exposure to low doses of one or more EDCs may result in adverse effects that are not observed at higher doses. As a result, conventional risk assessment methods, which extrapolate high-dose effects to predict low-dose effects, are inadequate to assess the effect of EDCs, and current methodologies cannot be used to derive safe doses of these chemicals. *See* Evanthia Diamanti-Kandarakis et al., The Endocrine Society, Endocrine-Disrupting Chemicals: An Endocrine Society Scientific Statement 4 (2009), *available at* https://www.endocrine.org/~/media/endosociety/Files/Publications/Scientific%20Statements/EDC_Scientific_Statement.pdf ("…low doses may even exert more potent effects than higher doses").

21 *See* ChemTrust, Chemical Cocktails: Harmful Mixtures Upset Our Hormones 2 (2010), *available at* http://awsassets.panda.org/downloads/edc_chemical_cocktail_leaflet.pdf (stating that populations are regularly exposed to multiple EDCs). The effects of the individual chemicals in the "cocktail" of chemicals, to which humans and wildlife are exposed may be additive, synergistic, or even antagonistic, such that exposure to multiple EDCs may have a combined effects not observed in examination of the hazards of an individual chemical. *See id.*

22 See WHO, Children and Neurodevelopmental Behavioural Intellectual Disorders (NDBID) 1-4 (2011), *available at* http://www.who.int/ceh/capacity/neurodevelopmental.pdf (stating that exposure to EDCs during specific critical windows of a child's development can produce permanent adverse effects). Childhood exposure can occur pre-natally or post-natally through the presence of these chemicals in mother's blood or breast-milk, food, or indoor environment. *Id.*

23 *See e.g.* Casey E. Reed & Suzanne E. Fenton, *Exposure to Diethylstilbestrol During Sensitive Life Stages: A Legacy of Heritable Health Effects*, 99 Birth Defects Res. Part C Embryo Today 134, 134-146 (2013), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3817964/ (explaining that studies of the progeny of women exposed to EDCs during their first trimester of pregnancy show reproductive abnormalities occurred 20 times more frequently in their male grandchildren). These effects illustrate the dangers of EDCs for future generations and the complexity of the challenge for epidemiology: the adverse effect(s) of exposure might not be observed until several decades after exposure and may not affect the health of the person initially exposed. *Id.*

24 Diamanti-Kandarakis, *supra* note 20, at 4 (stating that polar bears in the arctic, frogs and other forms of wildlife have all exhibited unusual hermaphroditic traits).

25 *See e.g.*, *Regulatory Action on PFAS/LCPFAC Compounds*, Envtl. Prot. Agency, http://www.epa.gov/oppt/pfoa/pubs/pfas.html (last visited Apr. 28, 2014) (noting a final EPA rule allowing the continued use of a toxic chemical because there were no available alternatives).

26 *See e.g.*, S. REP. No. 94-698, at 5 (1976), reprinted in 1976 U.S.C.C.A.N. 4491, 4495 (stating it is more difficult to regulate a chemical after the public and economy has become reliant on it).

27 This observation is not limited to these chemicals. For earlier examples of the prospect of regulation driving businesses to innovate away from toxic chemicals. *See* Nicholas Ashford et. al., Environmental/Safety Regulation and Technological Change in the U.S. Chemical Industry (1979) (report to the National Science Foundation); Nicholas Ashford et. al., *Using Regulation to Change the Market for Innovation*, 9 Harv. Envtl. L. Rev. 419, 429-443 (1985).

28 Ashford et al., *supra* note 27, at 426.

29 COWI A/S, Data on Manufacture, Import, Export, Uses and Releases of Dibutyl Phthalate (DBP), as well as Information on Potential Alternatives to its Use 10-11 (2009), *available at* http://echa.europa.eu/documents/10162/13640/tech_rep_dbp_en.pdf (observing European Council for Plasticizers and Intermediates (ECPI)); Agency for Toxic Substances & Disease Registry, *DI-n-BUTYL PHTHALATE, Production, Import/Export, Use, and Disposal* (Jan. 3, 2013), *available at* http://www.atsdr.cdc.gov/ToxProfiles/tp135-c5.pdf; Peter M. Lorz, et. al., *Phthalic Acid and Derivatives*, *in* Ullmann's Encyclopedia of Industrial Chemistry (Wiley-VCH: Weinheim, 2002); Lowell Center for Sustainable Production, Phthalate Alternatives: Health and Environmental Concerns 4 (Jan. 2011), *available at* http://www.sustainableproduction.org/downloads/PhthalateAlternatives-January2011.pdf.

30 COWI A/S, *supra* note 29, at 10.

31 Nat. Acad. Sciences, Phthalates and Cumulative Risk Assessment: The Task Ahead (2008), *available at* https://download.nap.edu/catalog.php?record_id=12528; Melissa Lee Phillips, *Phthalates and Metabolism: Exposure Correlates with Obesity and Diabetes in Men*, 115 Envtl. Health Persp. A312 (2007), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1892143/pdf/ehp0115-a0312b.pdf; Stahlhut, et. al., *Concentrations of Urinary Phthalate Metabolites Are Associated with Increased Waist Circumference and Insulin Resistance in Adult U.S. Males*, 115 Envtl. Health Persp. 876, 876-82 (2007), *available at* http://www.ncbi.nlm.nih.gov/pmc/articles/PMC1892109/pdf/ehp0115-000876.pdf.

32 Andreas Kortenkamp et. al, State of the Art Assessment of Endocrine Disruptors 65 (2012), *available at* http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf (report comissioned by the Directorate-General for the Environment of the European Commission); Y.Y. Chou, et. al., *Phthalate Exposure in Girls During Early Puberty*, 22 J. Pediatric Endocrinoogy & Metabolism 69, 69-77 (2009).

33 Matthias Wittassek, *et. al*, *Assessing Exposure to Phthalates – the Human Biomonitoring Approach*, 55 Molecular Nutrition & Food Res. 7, 7-31 (2011).

34 *See Authorisation*, European Chemicals Agency, http://echa.europa.eu/regulations/reach/authorisation (last visited Apr. 16, 2014) (explaining that chemicals that are substances of very high concern ("SVHCs") are nominated to be placed on the Candidate List. From here, the European Chemical Agency ("ECHA") can nominate certain chemicals for the Authorization List, where all uses, except for Authorized uses, of the listed chemical are to cease by a certain (sunset) date. Alternatively, EU Member States can nominate a chemical for the Restriction List).

35 *See Authorization List,* European Chemicals Agency, http://echa.europa.eu/addressing-chemicals-of-concern/authorisation/recommendation-for-inclusion-in-the-authorisation-list/authorisation-list (last visited Apr. 16, 2014)

36 Commission Regulation 1907/2006, of the European Parliament and of the Council, *Regulation of 18 December 2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency*, 2006 O.J., (L 396) 3, *available at* http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2007:136:0003:0280:en:PDF ("This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and *innovation.*").

37 *See* Nicholas Ashford & George Heaton Jr., *Regulation and Technological Innovation*, 46 Law & Contemp. Probs. 109, 139 (1983) (detailing the study of past experience about the influence of informal regulatory procedures). Although prohibited under the patent laws of many countries, it is possible that the inventions were known years beforehand, but not filed until enactment of regulation appeared imminent.

38 European Comm'n, *Commission Recommendation on Childcare Articles and Toys Intended to be Placed in the Mouth by Children of Less than Three Years of Age, Made of Soft PVC Containing Certain Phthalates,* 35-37 (July 1, 1998) *available at* http://eur-lex.europa. eu/LexUriServ/LexUriServ.do?uri=OJ:L:1998:21 7:0035:0037:EN:PDF.

39 Ashford & Heaton, *supra* note 37, at 139.

40 *Testing Services*, *REACH Authorization 2013*, Chem. Inspection & Regulation Serv., http://www.cirs-reach.com/Testing/REACH_SVHC_Authorization_Process.html (last updated April, 2013).

41 Ctr. for Strategy & Evaluation Services, Final Report, Interim Evaluation: Impact of the REACH Regulation on the Innovativeness of the EU Chemical Industry 48-52 (June 14, 2012), *available at* http://ec.europa.eu/enterprise/sectors.chemicals/files/reach/review2012/innovation-final-report_en.pdf [hereinafter REACH Innovation Report].

42 *Id.*

[43] Drug Discovery: A History 84-85 (Walter Sneader ed.,John Wiley & Sons, Inc. 2005); Stephen Andersen et al., Protecting the Ozone Layer: The United Nations History 8-9 (2007).
[44] *See, e.g.*, World Meteorological Org., *Assessment of our Understanding of the Processes Controlling its Present Distribution and Change*, 3 Atmospheric Ozone 649, 649 (1985), *available at* https://archive.org/details/nasa_techdoc_19860023425.
[45] *See* Andersen, *supra* note 43, at 10.
[46] Andersen, *supra* note 43, at 9.
[47] *See* Andersen *supra* note 43, at 10.
[48] Andersen, *supra* note 43, at 10.
[49] *See* Andersen, supra note 43, at 9.
[50] Montreal Protocol on Substances that Deplete the Ozone Layer, Sept. 16, 1987, 27 U.N.T.S. 1522.
[51] *See* Andersen, *supra* note 43, at 1, 21 (describing how interestingly, India and South Korea claimed they were unable to obtain licenses to HFC-134a on reasonable terms, raising a contentious issue in international environmental negotiations: the role of patents in enabling the development of environmentally sound technologies versus their potential to serve as a barrier to the wide-scale use of the technologies where appropriate).
[52] *See* Andersen, *supra* note 43, at 6-11.
[53] *See* Andersen, *supra* note 43, at 7.
[54] *See* Andersen, supra note 43, at 8.
[55] *See* Andersen, supra note 43, at 26.
[56] *See, e.g*., Kert Davies, *Greenfreeze F-Gas Victory! Greener Refrigerators Finally Legal in the U.S.*, Greenpeace (Dec. 14, 2011), *available at* http://www.greenpeace.org/usa/en/news-and-blogs/campaign-blog/greenfreeze-f-gas-victory-greener-refrigerato/blog/38405/ .
[57] Andersen, *supra* note 43, at 23.
[58] Andersen, *supra* note 43, at 21-22.
[59] Greenpeace Int'l., PVC-Free Future: A Review of Restrictions and PVC free Policies Worldwide 84 (9th ed. 2003), *available at* http://www.greenpeace.org/international/Global/international/planet-2/report/2001/8/pvc-free-future.pdf.
[60] *See e.g.* European Envtl. Agency*, Late Lessons, Early Warnings, volume I* (2002), *available at* http://www.eea.europa.eu; European Envtl. Agency, *Late Lessons, Early Warnings, volume II* (2013), *available at* http://www.eea.europa.eu; Richard Denison, *Won't we ever stop playing whack-a-mole with "regrettable chemical substitutions"?,* Chemicals & Nanomaterials (Jan. 12, 2010), *available at* http://blogs.edf.org/nanotechnology/2010/01/12/won%E2%80%99t-we-ever-stop-playing-whack-a-mole-with-%E2%80%9Cregrettable-chemical-substitutions%E2%80%9D/.
[61] John Owens, *The Truth about Flame Retardants*, The Chicago Tribune (2012), http://www.chicagotribune.com/videogallery/69743455/News/Video-The-truth-about-flame-retardants.
[62] "In studies on humans exposed to PCBs, effects on sperm motility, fetal growth rate (lower birth weight, smaller head circumference) and development (shorter gestational age, neuromuscular immaturity), and neurological functions of the offspring (impaired autonomic function, increased number of abnormally weak reflexes, reduced memory capacity, lower IQ scores, and attention deficit) have been observed. Epidemiological studies suggest exposure-related increases in cancers of the digestive system, especially liver cancer, and malignant melanoma." World Health Organization (WHO), *Polychlorinated Biphenyls: Human Health Aspects* (2003), *available at* http://www.who.int/ipcs/publications/cicad/en/cicad55.pdf.
[63] Toxipedia, Polybrominated Diphenyl Ethers (PBDEs) (webpage, last visited May 5, 2014) (citing Birbaum 2004), *available at* http://www.toxipedia.org/pages/viewpage.action?pageId=296.
[64] *Id*.
[65] PBDEs are restricted or banned under various national, regional and global laws, including the Stockholm Convention on Persistent Organic Pollutants. *See* Laura N. Van Den Berg, et al., *Hormones and Endocrine-Disrupting Chemicals: Low-Dose Effects and Nonmonotonic Dose Responses*, 33 Endocrine Reviews 378 (2012), *available at* http://edrv.endojournals.org/content/early/2012/03/14/er.2011-1050.full.pdf+html; *See also*, TEDX, *supra* note 15; *See e.g.* Diamanti-Kandarakis, *supra* note 19.
[66] *See e.g.* Safer Chemicals, Healthy Families, *supra* note 7.
[67] Stockholm Convention on Persistent Organic Pollutants, Adoption of Amendments to Annexes A, B and C, C.N.524.2009.TREATIES-4 (Depositary Notification), *available at* https://treaties.un.org/doc/Publication/CN/2009/CN.524.2009-Eng.pdf.
[68] Heather B. Patisaul, et al., *Accumulation and Endocrine Disrupting Effects of the Flame Retardant Mixture Firemaster 550 in Rats: An Exploratory Assessment*, 27 J.Biochemical & Molecular Toxicology 124, 124 (2013) (stating that Firemaster 550 ("FM 550") contains 2-ethylhexyl-2,3,4,5-tetrabromobenzoate ("TBB"), bis(2-ethylhexyl)-2,3,4,5-tetrabromophthalate ("TBPH"), triphenyl phosphate ("TPP") and several isopropylated triaryl phosphate isomers); Michael Hawthorne, *Toxic Roulette: Firemaster 550, Touted as Safe, is the Latest in a Long Line of Flame Retardants allowed onto the Market without Thorough Study of Health Risks*, Chicago Tribune, May 10, 2012, *available at* http://articles.chicagotribune.com/2012-05-10/business/ct-met-flames-regulators-20120510_1_flame-retardants-ban-chemicals-chemical-safety-law. .
[69] Hawthorne, *supra* note 68.
[70] Hawthorne, *supra* note 68.
[71] Hawthorne, *supra* note 68.
[72] See e.g., Patisaul et al., *supra* note 68.
[73] *See e.g.* Patisaul et al., *supra* note 68 (revealing for the first time, the potential for perinatal Firemaster 550™ exposure to have adverse effects indicative of endocrine disruption at levels much lower than the "No Observed Adverse Effect Level" ["NOAEL"] reported by the manufacturer. These findings are significant because Firemaster 550™ appears to be one of most commonly used replacements for PBDEs in foam and is prevalent in house dust.).
[74] *See*, Klaus Kummerer, Green and Sustainable Pharmacy, Rational Design of Molecules by Life Cycle Engineering 135, 143 (2007).
[75] *See, e.g.* ICLEI, Sustainable Procurement Guidelines: Cleaning Products and Services Background Report 8, (2008) *available at* http://ec.europa.eu/environment/gpp/pdf/toolkit/cleaning_GPP_background_report.pdf.
[76] *Id.* at 33.
[77] *See* The Ecological Council, Hazardous Chemicals Can Be Substituted-Developments Since 2006, 18 (2012).
[78] *See Id.*, at 16 (2012); *See also* Lowell Center for Sustainable Production, *supra* note 28, at 12 (providing a more detailed description of this product).
[79] *See* The Ecological Council, *supra* note 77, at 18; Lowell Center for Sustainable Production, *supra* note 29, at 9.
[80] *See* The Ecological Council, *supra* note 77, at 44.
[81] *See e.g*., Doug Smock, *Shift Out of PVC Relies on Proprietary Welding Process*, Plastics Today (April 20, 2012), http://www.plasticstoday.com/articles/shift-out-pvc-relies-proprietary-welding-process0420201201.
[82] Michael Hawthorne, *Testing Shows Treated Foam Offers No Safety Benefit: Fire-Resistant Barriers May Do Better Job, Cut Chemical Exposure*, chicago tribune (May 06, 2012), *available at* http://articles.chicagotribune.com/2012-05-06/news/ct-met-flames-barriers-20120506_1_flame-retardants-furniture-foam-smoke-detectors.
[83] REACH Innovation Report, *supra* note 41, at 23.
[84] REACH Innovation Report, *supra* note 41, at 13.
[85] Figure 1, *supra*.
[86] For example, under the U.S. Phthalates Action Plan, U.S. EPA intended to initiate rulemaking in autumn 2010 to add eight phthalates to the Concern List under the Toxic Substances Control Act section 5(b)(4) as chemicals that present or may present an unreasonable risk of injury to health or the environment. Also, Japan's Department of Food Sanitation, acting on a recommendation by the country's Ministry of Health, Labour and Welfare, issued a directive against the use of vinyl gloves with DEHP in food service kitchens. *See e.g.* U.S. EPA, Phthalates Action Plan Summary (webpage, last accessed May 5, 2014), *available at* http://www.epa.gov/oppt/existingchemicals/pubs/actionplans/phthalates.html.
[87] *See e.g.* Allen Godwin, Exxonmobile Chem. Co. Uses of Phthalates and Other Plasticizers (July 26, 2010), *available at* https://www.cpsc.gov/PageFiles/126379/godwin.pdf (presenting to U.S. EPA).
[88] Ashford et al., *supra* note 27, at 420-26.
[89] Oslo Manual, *supra* note 2, at 136.
[90] OECD, *supra* note 1, at 78,79.
[91] OECD, *supra* note 1, at 88.
[92] Laffont, J.J., *The New Palgrave Dictionary of Economics*, The New Palgrave Dictionary of Economics Online (Steven N. Durlauf et al. eds. 2d ed. 2014) http://www.dictionaryofeconomics.com/article?id=pde2008_E000200&edition=current&q=laffont%2C%20externalities&topicid=&result_number=1 (defining "externalities").
[93] Some of UNEP's findings include: US $236.3 billion in global environmental costs from anthropogenic activity producing volatile organic compounds (VOCs); The total overseas development assistance (ODA) to general healthcare for sub-Saharan Africa is exceeded by the cost of inaction related to current pesticide use (US $6.2 billion) with projected costs rising to US $90 billion

for sub-Saharan Africa from 2015-2020; US $108 billion in IQ-based lost economic productivity due to children's exposures to lead in Africa, Latin America, and South East Asia; and US$ 634 million per year in lost productivity of commercial fisheries in China due to acute water pollution. *See Cost of Inaction Initiative*, UNEP, http://www.unep.org/hazardoussubstances/UNEPsWork/Mainstreaming/CostsofInactionInitiative/tabid/56397/Default.aspx (last visited Apr. 10, 2014).

94 OECD, *supra* note 1, at 150; Oslo Manual, *supra* note 2, at 78.

95 Andreas Kortenkamp et. al, State of the Art Assessment of Endocrine Disruptors 97 (2012), *available at* http://ec.europa.eu/environment/chemicals/endocrine/pdf/sota_edc_final_report.pdf (report comissioned by the Directorate-General for the Environment of the European Commission).

96 REACH Innovation Report, *supra* note 41, at 77.

97 REACH Innovation Report, *supra* note 41, at 66.

98 REACH Innovation Report, *supra* note 41, at 19.

99 REACH Innovation Report, *supra* note 41, at 36.

100 Ashford & Heaton, *supra* note 37, at 136-37 (citing several studies from the 1970s).

101 Ashford & Heaton, *supra* note 37, at 138.

102 REACH Innovation Report, *supra* note 41, at 33.

103 REACH Innovation Report, *supra* note 41, at 72.

104 *See* REACH Innovation Report, *supra* note 41, at 71-75 (emphasis added).

105 *See* REACH Innovation Report, *supra* note 41, at 76, 81.

106 *See* REACH Innovation Report, *supra* note 41, at 16, 70.

107 *See* REACH Innovation Report, *supra* note 41, at 36.

108 *See* REACH Innovation Report, *supra* note 41, at 10.

109 Our patent landscape study showed that from 1972-2011, most inventions went beyond the scope of laws to restrict the use of phthalates, including coating, paints, and resins, as well as polyvinyl chloride (PVC) and plastics generally.

Endnotes: The Minamata Convention on Mercury: Past, Present, and Future Environmental Health

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have lost their livelihoods. *Minamata Disease Archives: Pathway of Methylmercury from Factory to Human*, Japan Ministry of Env't (2014), http://www.nimd.go.jp/archives/english/tenji/a_corner/a06.html.

8 *See generally* Nat'l Research Council, Toxicological Effects of Methylmercury 4-7 (2000), *available at* http://www.nap.edu/openbook.php?record_id=9899&page=R1.

9 Normile, *supra* note 4, at 1447.

10 Normile, *supra* note 4, at 1447.The Japanese government has recognized 2,265 victims of methylmercury poisoning; however, many people who suffered from smaller exposures to the toxin or have lesser health effects still go unrecognized. *Id.*

11 Normile, *supra* note 4, at 1446.

12 *See* Normile, *supra* note 4, at 1446. *Compare Minamata Disease Related Sights*, Japan Guide, http://www.japan-guide.com/e/e4527.html (last visited Feb 18, 2013) *with Minamata Disease Archives Factsheet*, Japan Ministry of Env't (2014), *available at* http://www.nimd.go.jp/archives/english/outline/leaflet_jyoho.pdf.

13 Joseph DiGangi, *Opinion: A Call for Action in Minamata*, Environmental Health News (Oct. 10, 2013), http://www.environmentalhealthnews.org/ehs/news/2013/a-call-for-action-in-minamata.

14 Minamata Convention on Mercury, Nov. 6, 2013, UNEP(DTIE)/Hg/INC.5/7*, *available at* http://www.mercuryconvention.org/Portals/11/documents/conventionText/Minamata%20Convention%20on%20Mercury_e.pdf.

15 Naomi Lubick & David Malakoff, *With Pact's Completion, The Real Work Begins*, 341 Science 1443, 1443 (2013).

16 *Id.*

17 *Id.* at 1443-44.

18 Krabbenhoft & Sunderland, *supra* note 7, 1458.

19 *See* Minamata Convention on Mercury, *supra* note 14, at art. 21 (outlining Parties' reporting requirements).

20 Lubik & Malakoff, *supra* note 15, at 1443.

21 Krabbenhoff & Sunderland, *supra* note 7, at 1458.

22 *See* Lubick & Malakoff, *supra* note 15, at 1445 (explaining that Parties to the Mercury Convention could develop a coordinated database, similar to that developed under the 2001 Stockholm Convention on Persistent Organic Pollutants, to record biomonitoring and infrastructure data for mercury).

23 Lubick & Malakoff, *supra* note 15, at 1445.

24 Lubick & Malakoff, *supra* note 15, at 1443.

25 *See* Lubick & Malakoff, *supra* note 15, at 1445.

26 Lubick & Malakoff, *supra* note 15, at 1445.

27 Lubick & Malakoff, *supra* note 15, at 1445.

28 Lubick & Malakoff, *supra* note 15, at 1445; *see also* Minamata Convention on Mercury, *supra* note 14, at art. 13 (outlining the Convention's mechanism for sharing financial resources).

29 Lubick & Malakoff, *supra* note 15, at 1445 ("Countries still need to work out what kinds of data to collect . . . .").

30 Lubick & Malakoff, *supra* note 15, at 1445.

31 *See supra* notes 19, 23 and accompanying text.

32 Lubick & Malakoff, *supra* note 15, at 1445.

33 Lubick & Malakoff, *supra* note 15, at 1445.

34 For example, unlike measuring ozone depletion, utilizing a variety of different methods or sample sources used to measure mercury may skew results. Lubick & Malakoff, *supra* note 15, at 1445 ("An alternative [to blood samples] might be gathering hair or urine samples, but recent research has shown that each might accumulate a different record of mercury exposure, potentially skewing results.").

Endnotes: Rubber-Stamped Regulation: The Inadequate Oversight of Genetically Engineered Plants and Animals in the United States

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an important opening for covering innovations in biotechnology and genetic engineering); 35 U.S.C. § 101 (2011).

18 Fernandez-Cornejo, *supra* note 16, at 19 (explaining the act established the International Union for the Protection of New Varieties of Plants to ensure that breeders of new varieties of plants were provided with the appropriate intellectual property rights).

19 7 U.S.C. § 2483 (2010); USDA, Plant Variety Protection Act and Regulations and Rules of Practice 14 (2006).

20 7 U.S.C. § 2543 (2011); USDA, *supra* note 19, at 19.

21 Diamond v. Chakrabarty, 447 U.S. 303 (1980) (deciding to extend patent rights to genetically engineered microorganisms, which are important tools and products of biotechnology, and strengthen the rights of breeders).

22 The USDA defines "transgenic organism" as an "organism resulting from the insertion of genetic material from another organism using recombinant DNA techniques." *Glossary of Agricultural Biotechnology Terms*, U.S. Dep't of Agric. http://www.usda.gov/wps/portal/usda/usdahome?navid=BIOTECH_GLOSS&navtype=RT&parentnav=BIOTECH (last updated Feb. 27, 2014).

23 Franklin Costantini & Elizabeth Lacy, *Introduction of a Rabbit B-globin Gene into the Mouse Germ Line,* 294 Nature 92, 92-94 (1981).

24 Fernandez-Cornejo, *supra* note 16, at 19 (noting that several rulings by the U.S. Patent Office extended intellectual property rights to a wide range of new biotechnology products such as seeds, plants, plant parts, genes, traits, and biotechnology processes).

25 Robert Hammer, et al. *Production of Transgenic Rabbits, Sheep and Pigs by Microinjection,* 315 Nature 680, 680 (June 1985).

26 51 Fed. Reg. 23302. (June 26, 1986).

27 Shoemaker, *supra* note 7, at 9.

28 *History of Biotechnology and Regulatory Services*, USDA APHIS, http://www.aphis.usda.gov/wps/portal/banner/help?1dmy&urile=wcm%3apath%3a/